UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)
October 31, 2013

DP BARCODE(s): **413231**

MRID(s) : **49011601, 49011603**

SUBJECT: (Name of Product) **Lysol Brand Disinfectant Direct Multipurpose Cleaner**

FILE REG# : **777-66 (secondary 777-91)**

DOCUMENT TYPE: Product Chemistry Review of New Product

PRODUCT TYPE: Non-Food, Ready to Use, End Use

INGREDIENTS:

PC Code	CAS #	Ingredient Name
069105	68424-85-1	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)
128928	63449-41-2	Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C8, C10, and C18)

TEST LAB: Reckitt Benckiser, LLC.

SUBMITTER: Reckitt Benckiser, LLC.

GUIDELINE: OCSPP 830 Guidelines – Product chemistry Parts A and B

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

DATE APPROVED: October 31, 2013

COMMENT: Reformulation of two existing registered products to reduce VOCs. Data submitted to support formulation changes being made to 777-66 and secondary 777-91.

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Antimicrobials Division (AD)
October 31, 2013

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg#: **777-66 (secondary 777-91)**
Product Name: **Lysol Brand Disinfectant Direct Multipurpose Cleaner**
DP Barcode(s): **413231**

CODE: (A570) Amendment, Non-fast track, Requiring Data Review

DATE DUE: November 19, 2013

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Velma Noble PM331/Tracy Lantz
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Reckitt Benckiser, LLC

PRODUCT FORMULATION FROM PROPOSED LABEL:

Active Ingredient(s):	% by wt.
Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C8, C10, and C18)	0.0860
Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)	0.0216
Other Ingredient(s):	99.8924
Total:	100

BACKGROUND:

Reckitt Benckiser, LLC has submitted an application to amend the registration of their product EPA Reg# 777-66 "Lysol Brand Disinfectant Direct Multipurpose Cleaner". The amendment is to provide an alternate formulation to lower the VOCs (volatile organic compounds) present in the product to meet new requirements. This registrant has submitted data to support this reformulation.

The product is a ready to use non-food use general purpose cleaner and disinfectant.

The product chemistry data package consists of the following:

1. Cover and Transmittal from Reckitt Benckiser, LLC dated May 14, 2013.
2. Confidential Statements of formula (CSFs).
    a. CSFs of alternates for EPA Reg# 777-66 dated July 24, 2013
        i. #1 (Formula 1955-003-Lemon).
        ii. #2 (Formula 1967-019A–Fresh Energy).
        iii. #3 (Formula e0002-124-Dye/Fragrance Free).
    b. CSFs of alternates for EPA Reg# 777-91 dated June 26, 2013
        i. #1 (Formula 1967-019B- Citrus).
        ii. #2 (Formula e0002-124-Dye/Fragrance Free).
3. Two Product Chemistry Study Documents.

MRID	Citation	Receipt Date
49011601	Giovinco, L. (2012) Lysol Brand Disinfectant Direct Multi Purpose Cleaner: Honey - APC Trigger Spray - Formulation No. 1955-003: Product Properties-Groups A & B. Unpublished study prepared by Reckitt Benckiser, LLC. 110p.	28-Jun-2013
49011603	Genardi, L. (2012) Verification of Test Method and Chemical Characterization for Formula 1955-003. Project Number: 2012/0023/OCR. Unpublished study prepared by Reckitt Benckiser, Inc. 21p.	28-Jun-2013

FINDINGS:

1. Confidential Statement s of Formula. A complete set of CSFs were submitted for both products (777-66 and 777-91) which are subject to the formulation changes.

    a. These formulation changes do not result in changes to the nominal concentrations of the active ingredients or certified limits – and therefore should not result in any changes to the label ingredient statement.
    b. All inert ingredients and mixtures in both products are found acceptable for non-food use pesticide products.
    c. The alternate formulations appear to be substantially similar except for alternate fragrances or being fragrance free.

2. Product Label. The proposed formulation changes should not result in any label changes. No label was submitted for review.

3. Product Chemistry Groups A and B

    a. Product Identity and Composition: The Product Chemistry Group A studies as submitted are not typically considered as being required to support new alternate formulations for an already registered product. In the case of OCSPP 830.1650 Formulation Process, when a revised product formulation process is submitted for an already registered product, it is usually considered that the process should supersede existing formulation methods. An original formulation process could not be found for either of these products (777-66 or 777-91). This product's formulation process is a seemingly simple one that should result in a minimal change to resultant formulation. These descriptions in the product chemistry group A study document are found to be acceptable.

    b. Physical and Chemical Properties.

        i. Because of the limited nature of change in the formulation process group B requirements were limited to those listed in the Table B (below). Study results are acceptable.

        ii. Confirmatory storage stability and corrosion characteristics studies are ongoing. Preliminary 3 month data performed as 25 and 40°C are well within EPA standard certified limits (± 10%) total quaternary.

CONCLUSION:

The three new alternate CSFs for EPA Reg# 777-66 dated July 24, 2013 as well as the two alternate CSFs for EPA Reg#: 777- 91 dated July 26 are found acceptable. The Product Chemistry Group A studies as well as Group B studies are acceptable, however there exists a data gap in the storage stability and corrosion characteristics studies because only preliminary 3 month data was submitted. The final results of the complete 12 month stability studies must be submitted for review upon completion.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system — Yes [ ] No [X][
- Are all TGAIs used registered? — Yes [ ] No [X]
- Integrated formulation system — Yes [X] No [ ]

b. Clearance of inerts for non-food or food use:

The product is non-cleared for food use under 40 CFR §§180.940 and 180.950.

Yes [ ] No [x]

Note: This product is not intended for food use. All inert ingredients have PC codes. All formulation components are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," available at http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf.

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No [ ]

e. Nominal and Certified Limits:

Note: EPA standard certified limits. .

f. Active ingredients

Active Ingredient	Nominal%	Lower CL%	Upper CL %
Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C8, C10, and C18)	0.0860	0.0774	0.0946
Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)	0.0216	0.0194	0.0237

g. For products produced by an integrated formulation system

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL: No label changes proposed as part of this amendment.

a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [ ] No [ ]

b. The formula contains one of the following:

• 10% or more of a petroleum distillate:	Yes [ ]	No [X]
• 1.0% or more of methyl alcohol:	Yes [ ]	No [X]
• sodium nitrite at any level:	Yes [ ]	No [X]
• a toxic List 1 inert at any level:	Yes [ ]	No [X]
• arsenic in any form:	Yes [ ]	No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes [ ] No [ ] Not applicable [X]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes [x] No [ ]

Note: The one year storage stability and corrosion characteristics studies are underway. Preliminary 3 month results were submitted and found acceptable.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A-	49011601CSF
830.1600 Description of Materials	A	49011601
830.1620 Production Process[2]	NA	49011601
830.1650 Formulation Process	A	49011601
830.1670 Formation of Impurities[4]	A -	49011601
830.1700 Preliminary Analysis[5]	NA	
830.1750 Certified Limits[6]	A – EPA Standard certified limits A- A signed certification statement was provided, as requested under OPPTS 830.1750(g).	49011601and CSF
830.1800 Enforcement Analytical Method[7]	A – Titration.	49011603
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	49011601

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6317 Storage Stability	G- study Incomplete Preliminary results acceptable	Preliminary 3 month results provided. Performed at 25 and 40 °C Total Quaternary (average) Initial = 0.111 3 month 25°C = 0.114 (Δ + 2.9) 3 month 40°C = 0.115 (Δ + 3.5)Δ Changes within Δ ± 10% CL	49011601
830.6319 Miscibility[1]	A	Not an emulsifiable liquid, intended to be used in aqueous systems.	49011601
830.6320 Corrosion Characteristics	G – study incomplete Preliminary results acceptable	Study is underway. Three month preliminary data at 25 and 40 °C indicates both product and container show no changes in appearance or signs of degradation..	49011601
830.6321 Dielectric Breakdown Voltage	A	The end use product is not intended for use in or around electrical equipment.	49011601

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water